K021094

JUL 3 2002

7.0 510(k) Summary

SUBMITTER:

B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109-9341
(610) 266-0500, ext. 2280

Contact: Patricia D. Wilson, Regulatory Affairs Specialist

DEVICE NAME: Introcan® Safety™ IV Catheter

COMMON OR USUAL NAME: Safety Intravascular Catheter / Safety Introducer Catheter

DEVICE CLASSIFICATION: Class II, 21 CFR § 880.5200: Intravascular Catheter and 21 CFR § 870.1340: Catheter Introducer

PREDICATE DEVICE:
B. Braun Medical Inc. Introcan Safety IV Catheter (K982805)
B. Braun Medical Inc. Introducer Catheter (Kit component of K810460 / K810461)
Becton Dickinson Infusion Therapy Systems Inc., BD Introsyte™ Autoguard™ Shielded Introducer (K013304)

DESCRIPTION: The Introcan Safety IV Catheter consists of an over-the-needle catheter with a safety clip feature. Upon removal of the needle from the catheter, the safety clip is automatically secured over the needle tip as it exits the catheter hub. The Introcan Safety IV Catheter is available in sizes ranging from 14 Gauge through 24 Gauge.

INTENDED USE: The Introcan Safety IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

SUBSTANTIAL EQUIVALENCE: The Introcan Safety IV Catheter includes the same materials, construction, design, and safety clip feature as the Introcan Safety IV Catheter previously cleared under the B. Braun Medical Inc. Premarket Notification, K982805. The Introcan Safety IV Catheter is also similar in materials and design, with the exception of the safety clip feature, as the introducer catheter previously cleared as a kit component under the B. Braun Medical Inc. Premarket

K021094

Notifications, Burron Percutaneous Introducer Set (K810460) and Burron Central Vein Catherization Kit (K810461). The new indication for the Introcan Safety IV Catheter, for use as an introducer catheter, is the same indication previously cleared for Becton Dickinson Infusion Therapy Systems Inc.'s Premarket Notification, BD Introsyte™ Precision Introducer, BD Introsyte™ Autoguard™ Shielded Introducer, K013304.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2002

B. Braun Medical, Inc
c/o Ms. Patricia D. Wilson
Regulatory Affairs Specialist
901 Marcon Boulevard
Allentown, PA 18109-9341

Re: K021094
Introcan® Safety™ IV Catheter
Regulation Number: 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: April 3, 2002
Received: April 4, 2002

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

510(k) Number (if known): K021094

Device Name: Introcan® Safety™ IV Catheter

Indications For Use:

The Introcan® Safety™ IV Catheter is a passive anti-needle stick device to provide venous or arterial access for the infusion of fluids, drugs, and/or blood components, or to facilitate the placement of Vascular Access devices such as guidewires, indwelling central venous catheters, peripherally inserted central catheters, and midline catheters into the vascular system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices
510(k) Number K021094